Stage-Gate and successful commercializing of novel ingredients in the food and beverage market

by

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B.S., University of Tennessee, 2008

A THESIS

Submitted in partial fulfillment of the requirements

for the degree

MASTER OF AGRIBUSINESS

Department of Agricultural Economics

College of Agriculture

KANSAS STATE UNIVERSITY

Manhattan, Kansas

2026

Approved by:

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ABSTRACT

The novel food ingredient market is projected to grow from $33 billion to over $106 billion in the next decade. Commercializing new food ingredients currently requires experts to navigate complex technical, regulatory, and market barriers, often without a structured framework to guide decision-making. This study examines the current literature on ingredient commercialization and integrates it with empirical data collected from a survey of senior industry professionals with direct experience launching novel food ingredients. Twenty qualified respondents across regulatory, innovation, R&D, manufacturing, business development, and executive leadership roles completed an anonymous 26-question survey covering stage-based risk, failure drivers, decision gates, and key performance indicators.

Findings indicate that commercialization risk is not evenly distributed across stages. Downstream adoption emerged as the highest-risk stage and the primary determinant of success, followed by regulatory strategy and manufacturing scale-up. First customer adoption was identified as the single most critical success factor, while time to scale was consistently underestimated across respondents. In addition, organizational misalignment and weak downstream demand were identified as perceived leading root causes of failure, exceeding technical or capital-related constraints. Securing downstream customer commitment and achieving regulatory clarity were consistently identified as the most critical decision gates, reinforcing that commercialization success is driven more by market-adoption readiness than by technical validation alone.

To address the lack of a structured commercialization strategy, this study develops and applies the Hazard Analysis and Critical Control Point (HACCP) framework, traditionally used in food safety, as a stage-based model for managing commercialization risks. By identifying the critical control points across developmental stages, a HACCP approach provides a systematic way to monitor, mitigate, and manage commercial risks. The proposed framework, based on pilot study and not inferring broader conclusions, offers a practical tool for improving decision-making and increasing the likelihood of successful market adoption of novel food ingredients.

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ACKNOWLEDGMENTS

I would like to express my sincere gratitude to the faculty and staff of Kansas State University's Agribusiness and MBA programs for their guidance, support, and dedication throughout this program. Their commitment to student success and academic excellence has been instrumental in my experience.

I am especially grateful to my thesis advisor, Dr. V (Dr. Vincent Amanor-Boadu), for his mentorship, flexibility, and continued support throughout the development of this work. His guidance, insight, and willingness to accommodate the demands of both academic and professional responsibilities were critical to the completion of this thesis.

Finally, I would like to thank my family for their unwavering support throughout this journey. In my earlier years, before motherhood, small business ownership, and a separate full-time career, my personal motto often echoed James Agee's sentiment: "A little too much is just enough for me." While that philosophy may once have defined my pace, this chapter of my life required something different. I once had the flexibility to ebb and flow as demands came, but completing this program required a far more deliberate approach. Every aspect of this process, from writing papers to preparing for exams, was mindfully scheduled and coordinated across family calendars and work schedules.

I am deeply grateful for my husband's resilience, patience, and understanding, particularly during the many evenings I stepped away to focus on this degree. His support made it possible to see this through. With this milestone complete, I can confidently say that I have fulfilled that inclination and have no immediate plans to revisit "a little too much" anytime soon.

GLOSSARY OF TERMS USED IN THE THESIS

Adoption (Downstream Adoption): The process by which a customer integrates a novel ingredient into a commercial product and continues its use over time. In this study, adoption is the primary determinant of commercialization success.

Commercialization: The process of bringing a novel ingredient from development to market, including technical validation, regulatory approval, manufacturing scale-up, and sustained customer adoption.

Cost Competitiveness (Cost-in-Use): The ability of an ingredient to meet the economic requirements of the target application, considering formulation inclusion rates, performance, and price relative to alternatives.

Critical Control Point (CCP): A stage in the commercialization process where failure risk is highest and must be actively managed before proceeding. Adapted from HACCP principles.

Derived Demand: Demand for an ingredient that is dependent on the demand for the final product in which it is used.

Downstream Adoption: The stage of commercialization where ingredient customers (e.g., food manufacturers) evaluate, approve, and implement the ingredient into their products.

Equality of Proportions Test: A statistical method used to determine whether differences in proportions between groups (e.g., role types) are statistically significant.

HACCP (Hazard Analysis and Critical Control Points): A structured risk management framework traditionally used in food safety, adapted in this study to identify and manage commercialization risks across stages.

Intellectual Property (IP): Legal protections (e.g., patents, trade secrets) that prevent competitors from replicating an innovation, supporting competitive advantage.

Novel Ingredient: An ingredient that is new in functionality, production method, or application within a given market, often requiring additional validation, regulatory approval, and adoption effort.

Pecuniary Costs: Direct financial expenditures associated with commercialization, including R&D, manufacturing, regulatory, and marketing costs.

Non-Pecuniary Costs: Indirect costs such as time, opportunity cost, organizational resources, and risk associated with commercialization activities.

Stage-Gate Process: A structured innovation process where development progresses through defined stages separated by decision points ('gates') that determine whether to proceed.

Stakeholder Alignment: The degree to which decision-makers in different units (e.g., R&D, regulatory, commercial, operations) are coordinated in decision-making during commercialization.

Technical Validation: The process of confirming that an ingredient performs as intended under real-world application conditions.

VRIN Framework: A strategic framework stating that resources must be **V**aluable, **R**are, **I**nimitable, and **N**on-substitutable to provide sustained competitive advantage.

Value Innovation: A strategy that simultaneously increases customer value while reducing costs, enabling competitive differentiation and scalability.

Scale-Up (Manufacturing Scale-Up): The transition from pilot or laboratory production to commercial-scale manufacturing with consistent quality, cost, and supply reliability.

Time-to-Scale: The duration for an ingredient to move from development to commercially viable production volumes.

GRAS (Generally Recognized as Safe): A regulatory designation in the United States indicating that a substance is considered safe under the conditions of its intended use based on scientific consensus.

Regulatory Pathway: The defined process and requirements needed to obtain approval or clearance for an ingredient to be used in a specific market.

Cost Target: The predetermined cost level required for an ingredient to be viable within a specific application or market.

Deployment: The ability to scale and operationalize an ingredient across multiple customers or markets after initial adoption

CHAPTER I: INTRODUCTION

1.1 Background

Developing novel food ingredients is a rare and costly process. Yet the global novel food ingredients market is reportedly growing rapidly – expected to reach $106.5 billion in 2033 from about $32.2 billion in 2024 (PR Newswire, 2025). The processes of problem identification, market gap assessment, solution development, and product realization all occur under conditions of uncertainty. This increases both financial and failure risk. Once a product is developed, it undergoes regulatory review to establish the necessary pathways and supported claims. These steps influence how it is marketed and help recover its investments. These early decisions create path dependencies that shape strategic options, market positioning, and profitability timelines. They are, however, nonlinear, since information from later stages may be used to improve earlier stages and to revisit the decision processes.

It is evident that there are both pecuniary and non-pecuniary costs. Some of the pecuniary expenditures include salaries for personnel involved in research and development, procurement of specialized equipment, machinery, tools, and consumables such as reagents and chemicals. They also include manufacturing and scaling costs, launch costs, and marketing and selling costs. Non-pecuniary expenditures encompass time, both lead time to a solution and lag time to adoption and deployment, as well as the opportunity cost and risk associated with committing organizational resources under uncertain conditions. Collectively, these costs make launching novel products very expensive. These commercialization costs are estimated to reach about $10 million per product (Le Bloch, et

al., 2025). This could result in an estimated total failure cost of £30.4 (about $40.5) million per year in the grocery industry alone (FMCG, 2017).

In fairness, not all novel ingredients are value innovations, which are defined as innovations that simultaneously increase customer value and reduce supplier costs (Kim & Mauborgne, 1997). Value innovations may take different forms depending on whether they leverage existing production and organizational systems or require the creation of new ones. In cases where innovation is achieved through recombination or extension within established infrastructures, increases in customer value can be realized alongside favorable cost dynamics through scale, asset utilization, or efficiency gains. By contrast, novel products that require developing new systems, capabilities, or processes may generate meaningful customer value but face higher commercialization risk due to elevated upfront costs and delayed economic returns.

The ability of a novel product to translate value innovation into sustained commercial success, therefore, depends not only on the value it creates but also on the underlying characteristics that allow it to withstand competitive imitation, adoption friction, and scaling pressures. The inherent characteristics of such offerings include the following: Valuable, Rare, Inimitability, Non-Substitutability, and durability over time (Barney, 1991). Solutions with these characteristics are more likely to achieve high adoption and deployment rates, high retention, and low churn. These high indicators contribute to scalability, providing the resources needed to sustain initial success (Mahoney & Pandian, 1992). The foregoing indicates that the successful commercialization of novel products in any industry, including the food and beverage industry, must begin with conceptualizing the value they will deliver to customers and producers. Any product that is not rooted in

value innovation is bound to experience commercialization challenges (Kim & Mauborgne, 1997).

In new product development, 'novel' is understood as something new, original, unique, or unprecedented. It means new to the space into which it is introduced (Kohler, 2008) While 'novel' can broadly describe any characteristic of a product that is new to the market or new in use, it is specifically used here to refer to the functionality of ingredients. The functionality of an ingredient refers to the specific contribution it makes to the food, such as changing characteristics like texture, flavor, structure, stability, safety, and nutritional value. For example, corn starch's functionality in soups and sauces may be to thicken, but in cakes, it could enhance binding. Generally, functional ingredients are defined as bioreactive compounds that offer benefits such as antioxidant, anti-inflammatory, and other protective or health-related properties (Temple, 2022). The characteristic of providing novel value increases their commercialization risk. Their development and production costs highlight the importance of understanding how to improve their chances of success.

1.2 Research Problem and Research Question

Companies launching novel ingredients into food and beverage markets face commercialization hardships and failures due to a poorly defined set of critical challenges and the absence of a structured framework for prioritizing and addressing them throughout the commercialization process. As a result, firms rely heavily on experience-based judgement from subject-matter experts rather than on systematic, repeatable frameworks. This pilot study examines how commercialization challenges with novel ingredient launches can be systematically identified, categorized, and prioritized to explain differences in launch outcomes.

Launch success is defined by the degree of adoption and deployment of the novel ingredient and its translation into acceptable financial performance for the firm. Specifically, a novel ingredient launch is considered successful if it generates a positive net present value, achieves a reasonable payback period, and delivers durable returns on invested capital. The question this research seeks to address is: How can the success of commercialization for novel food ingredients be improved through the careful development and implementation of a structured commercialization pathway?

1.3 Objectives

The overall objective of this pilot study is to develop a structured, strategic pathway for the commercialization of novel ingredients in food and beverage markets by systematically identifying, categorizing, and prioritizing the critical challenges that influence commercialization outcomes. The specific objectives are:

1. Identify and categorize the potential sources of failure risks at each stage of the solution development and commercialization process and then adapt the logic of Hazard Analysis and Critical Control Points (HACCP) to a strategic commercialization context.
2. Evaluate how perceptions about failure risks and commercialization success factors differ across decision roles in the ingredients commercialization industry.
3. Develop a solution to help the industry reduce failure risks and improve commercialization success using the familiar HACCP procedure commonly used in food manufacturing.

1.4 Methods

This study employs a qualitative, exploratory research design to examine the commercialization challenges associated with novel food ingredients and to develop a

structured commercialization pathway. The research integrates a review of existing literature with empirical data collected from industry professionals directly involved in ingredient commercialization.

Data were gathered through a structured survey of senior professionals across regulatory, research and development, manufacturing, business development, and executive roles. The survey focused on identifying stage-specific risks, failure drivers, decision gates, and key performance indicators influencing commercialization outcomes.

The findings were analyzed using descriptive statistics and comparative analysis to identify patterns across commercialization stages and roles. These insights were then used to develop a stage-based framework, adapted from Hazard Analysis and Critical Control Point (HACCP) principles, to systematically identify and manage commercialization risks. It is important that the results from this research are not meant to provide any inferential insights because of the research design. Rather, they are input into redesigning the survey (Appendix A) for a future study. A detailed description of the research design, data collection methods, and analytical approach is provided in Chapter 3 and reported in Chapter 4.

1.5 Outline of the Thesis

The next chapter presents an overview of the literature. The research methods and data collection processes are presented in Chapter 3. The findings from the research are presented in Chapter 4. The model that adapts the HACCP process for commercialization is developed and discussed in Chapter 5, along with the study's summary and conclusions.

CHAPTER II: LITERATURE SUMMARY

In this chapter, we present an overview of the commercialization literature, focusing on novel ingredients in the food and beverage industry. The chapter is organized into three sections. The first presents the context and definitions, given that commercialization differs across industries and activities. The second explores the novelty and scale of commercialization in the food and beverage industry regarding new ingredients, and the third focuses on the adoption dynamics of commercialized novel ingredients in the food and beverage industry.

2.1 Contextualizing Commercialization in the Food and Beverage Industry

The term *commercialization* is widely used in innovation and strategy research, yet its meaning varies substantially across disciplines and industries. In the context of novel ingredients, commercialization extends beyond product launch to include technical validation, repeatable adoption, scalable deployment, and sustained net-positive financial returns. These definitional differences matter because they shape managerial decision-making, the risks prioritized, the Key Performance Indicators (KPIs) used, and how success or failure is ultimately assessed.

The existing literature on innovation and new product development provides valuable insights into commercialization processes but offers limited guidance on systematically identifying, prioritizing, and managing the risks unique to novel ingredient launches. Food and beverage firms must simultaneously address technical feasibility, regulatory compliance, operational scalability, and customer adoption in highly cost-sensitive, reformulation-resistant markets. As a result, technically similar innovations often experience very different commercial results.

Accordingly, this chapter examines the literature on commercialization success, novelty, adoption dynamics, and risk to establish the theoretical foundation for this study. It is organized into three broad sections. The first section tackles the definitional challenge alluded to above. It seeks to assess the meaning of commercialization success for novel food ingredients. The second section reviews the literature on novelty, development and scale in food ingredients, and the final section focuses on the adoption dynamics and their influence on commercialization of novel food ingredients.

2.2 Defining Commercialization Success in Novel Food Ingredients

It is important to clarify immediately that success is more than just "launch completed". In the context of novel food ingredients, commercial success must be evaluated as a multi-stage process rather than as the achievement of technical success or initial market entry. If the launch fails to drive repeatable customer adoption or achieve a positive net present value, it should be considered unsuccessful. This is especially relevant in the food and beverage markets where customers are highly cost-sensitive or where the cost of time, due to reformulation, qualification, and supply assurance, can prevent adoption at a necessary pace to match market demands. This commercialization challenge is well captured in Kim and Mauborgne's value innovation framework (Kim & Mauborgne, 1997), which argues that long-term success depends on the strategic logic guiding the decision-making. In conventional strategy logic, firms will choose between differentiation and low cost, either offering superior performance at a higher cost or competing on cost at the expense of innovation. In contrast, the value innovation strategy logic rejects the trade-off by pursuing both increased buyer value and lower supplier costs.

For novel food ingredients, this distinction is imperative. An ingredient launched with conventional logic may deliver added functionality but will struggle to scale if the cost

of use exceeds what customers can absorb. By comparison, a value innovation approach prioritizes solutions that create meaningful differentiation while remaining economically and operationally viable at scale. McKinsey's work on biotech ingredients is a valuable example of a "great idea" that still struggles to achieve consistent commercial success (Daniel Aminetzah, 2025). The report argues that fermentation-derived biotech ingredients unlock billions in value but lack the infrastructure and are burdened by high-cost manufacturing with limited capacity. Significant capex projects are required to achieve cost competitiveness across the industry. If the manufacturing company cannot supply at commercial volumes, any value created is weakened, and adoption is unlikely to scale.

This paper reinforces the premise that any novel ingredient innovation must be evaluated based on scale and economic durability, not just technical feasibility or market entry. For this thesis, commercialization success is defined as achieving repeatable customer adoption, scalable deployment, and net-positive financial returns under real-world cost and supply constraints.

2.2.1. Sustained Commercial Advantage and VRIN

Once adoption occurs, commercialization success also depends on the durability of competitive advantages. Strategic management literature states that resources capable of achieving sustained advantage must possess VRIN characteristics: they must be valuable, rare, inimitable, and non-substitutable (Barney, Firm Resources and Sustained Competitive Advantage, 1991). When applied to novel food ingredients, this means that even successful product launches may fall short if they are easily replicated. Recent applications of the resource-based view (RBV) in food-related systems demonstrate how new inputs can be evaluated against VRIN criteria to assess their potential for long-term advantage.

Therefore, commercialization success includes adoption, scaling, and the ability to maintain differentiation in competitive environments.

2.3 Novelty, Development, and Scale in Food Ingredient Innovation

Innovation in food and beverage markets is often discussed at the finished-product level, where efforts are primarily focused on branding, marketing, regulatory compliance, and product placement. By contrast, ingredient-level innovation presents a fundamentally different set of challenges. Unlike consumer products, novel ingredients are intermediate goods whose value is realized indirectly through downstream manufacturing rather than through direct consumer demand. The demand for novel ingredients is determined, therefore, by the expectation of their contribution to final demand for the products the ingredients are used for, i.e., derived demand (Goel, 2020). Understanding the economics of the ingredients markets, prices, substitutes, complements, competitions, etc. all become critical in the definition of novelty and the development of the ingredient. As a result, ingredient innovation economics and strategy are often more complex than final product innovation. Ingredient innovation is subject to scrutiny across technical, regulatory, operational, and economic layers before market adoption can occur. The embedded risk in the process is further amplified by rapid functional imitation and the availability of substitute technologies, increasing the importance of early defensibility.

Regulatory frameworks often define novelty in geographic terms. For example, The EU classifies novel food ingredients as ingredients that have not been used in the production of foods to any significant level within a particular region (European Food Safety Authority, 2025). This means that an ingredient could be common in one region and be completely novel in another. It is this regional familiarity of food and food ingredients in the definition of their novelty that causes definitional challenges. While this regulatory

interpretation is important for regulatory pathways, it does not capture the type of novelty examined in this study.

Novelty in ingredient development can take multiple forms, including new raw material sources, new production processes, or new functional attributes (BIOSAFE, 2024). While such novelty can create meaningful differentiation, it also increases commercialization risk by introducing uncertainty across multiple dimensions simultaneously. Potential users of such novel ingredients must evaluate them within the context of their product markets (Scheibenzuber, et al., 2025). Ingredient buyers evaluate not only whether the ingredient performs as intended, but also whether it integrates reliably into existing formulations, processes, and supply chains (Gunden, Atakan, Yercan, Mattas, & Knez, 2024). These requirements increase adoption costs and timelines compared with incremental product innovation.

Research on scaling innovation emphasizes that achieving broad impact requires more than proof-of-concept, further distinguishing ingredient innovation from finished-product innovation (Woltering, Fehlenberg, Gerard, Ubels, & Cooley, 2019). Finished products can often be launched on a limited scale, tested in the market, and iterated rapidly. In contrast, novel ingredients must often demonstrate manufacturability, supply reliability, and cost stability at or near commercial scale before customers are willing to commit to adoption. This creates a paradox in which scale is needed to reduce costs, yet adoption is needed to justify investing in scale. As a result, many technically successful ingredients struggle to transition from pilot production to economically viable commercial volumes since it requires a strategic shift toward addressing real-world complexity and systemic constraints

The development and scale challenges associated with novel ingredients are further compounded by regulatory requirements. Ingredients must comply with safety and authorization frameworks before market entry, which can materially extend commercialization timelines. For example, under the European Union's Novel Food Regulation (Regulation (EU) 2015/2283), safety assessment and authorization by the European Food Safety Authority commonly takes multiple years, with published analyses indicating average approval timelines exceeding two years and some cases extending significantly longer due to iterative data requests and review cycles. These prolonged regulatory timelines delay market access even after technical feasibility has been established, amplifying the financial and operational risks associated with scaling novel food ingredients (Le Bloch, et al., 2025).

In contrast to the European Union's novel food authorization requirement, which prohibits market entry without prior approval, the United States uses the GRAS (Generally Recognized as Safe) determination process, which allows substances to be marketed based on established scientific evidence and consensus without full pre-market approval. This pathway, rooted in scientific procedures and historical use, can reduce time-to-market and lower upfront regulatory burden for novel ingredients in certain jurisdictions (Williams, Kobets, Iatropoulos, Duan, & Brunnemann, 2016).

Regulatory pathways, such as GRAS, serve not only as a safety determination but also as a risk-reduction mechanism for downstream adopters. When an ingredient firm establishes a broad scientific consensus regarding safety, GRAS status reduces regulatory uncertainty for food manufacturers, lowering barriers to adoption even when functional differentiation has already been demonstrated (George A. Burdock, 2006). As a result,

GRAS status is widely viewed by food manufacturers as a prerequisite for managing regulatory and liability risk when incorporating novel ingredients into commercial formulations. Taken together, novelty, scale, and regulatory burden explain why ingredient commercialization is structurally difficult, but they do not explain why failure often occurs after technical feasibility has been achieved. This gap highlights the roles of adoption dynamics and stakeholder decision-making in shaping commercialization outcomes.

2.4 Adoption Dynamics and Commercialization Risk

The adoption of novel food ingredients is shaped not only by technical performance but also by how downstream organizations evaluate and manage risk. Unlike finished products, where market acceptance can be tested directly through consumers, ingredient adoption decisions are made internally within food manufacturing organizations and typically involve multiple functional stakeholders, including research and development, regulatory affairs, quality assurance, procurement, and finance. Each function applies different evaluation criteria, increasing coordination requirements and extending decision timelines.

Research on new product development emphasizes that when multiple stakeholder issues must be addressed simultaneously, commercialization outcomes depend on how effectively organizations identify, coordinate, and prioritize these issues in their decision-making processes. Stakeholder integration literature distinguishes between market stakeholders, who focus on performance, cost, and usability; and nonmarket stakeholders, such as regulators and quality functions, who emphasize compliance, safety, and legitimacy in different ways (Driessen & Hillebrand, 2013). When organizations recognize the relevance of both, they are more likely to encounter conflicting priorities that require explicit trade-offs rather than incremental optimization (Driessen & Hillebrand, 2013).

For novel food ingredients, the adoption challenges discussed earlier are even more significant because these ingredients are intermediate products that must be approved, integrated, and justified by downstream manufacturers before entering the market. Benefits are gained indirectly through downstream products, while the risks of adoption are borne by manufacturers upfront (Driessen & Hillebrand, 2013). Consequently, commercialization outcomes for novel food ingredients often vary despite similar levels of technical progress. Ingredients may succeed in pilot development but fail to achieve sustained commercial deployment if stakeholder priorities are not effectively coordinated and addressed during downstream adoption processes (Driessen & Hillebrand, 2013). Therefore, adoption dynamics represent a distinct and important source of commercialization risk for novel food ingredients.

Although prior research identifies technical, regulatory, scaling, and adoption barriers, the literature remains fragmented across disciplines and lacks a structured framework for systematically identifying, prioritizing, and managing commercialization risks across development stages. Existing studies tend to examine individual constraints in isolation rather than offering an integrated pathway to guide the commercialization of novel ingredients. This gap motivates the development of the structured commercialization framework proposed in this study, which supports a stage-based approach to identifying and managing failure points, an approach adapted from HACCP principles

CHAPTER III: RESEARCH METHODS AND DATA

This chapter describes the research methodology used to develop a structured pathway for commercializing novel food ingredients. The chapter is organized into four sections. The first describes the design of the research and the second presents the adaptation of the stage-gate process and Hazard Analysis and Critical Control Points (HACCP) to the commercialization process. The third section describes the data collection process while the fourth presents the analytical methods employed.

3.1 Research Design

This study employs a qualitative, exploratory research design to create a structured commercialization framework based on theory and professional experience. The existing literature presents risk categories in a fragmented manner, often focusing separately on different internal functions such as regulatory issues or economies of scale. This approach enables an exploratory design to unify these aspects into a stage-based model.

This research aims to develop a decision framework that identifies key commercialization risk points and control mechanisms, rather than testing a predefined hypothesis. The qualitative approach enables in-depth analysis of professionals with direct experience and facilitates discussions among the various roles involved in ingredient commercialization, drawing on two sources of insight.

1. Theoretical foundations pulled from innovation, resource-based theory, stakeholder integration, scaling research, and regulatory economics (Chapter 2).
2. Empirical insight gained through interviews with seasoned C-suite and Senior Leadership professionals.

The goal is to identify recurring commercialization hazards, categorize them, and prioritize based on their severity and impact on adoption and financial performance.

3.2 Conceptual Adaption of HACCP to Commercialization

HACCP is a well-known and internationally recognized food safety management system designed to prevent, reduce, or eliminate hazards in food production. It is one of the first methods Food Scientists learn during undergraduate courses. This system assesses biological, chemical, and physical hazards at all stages of production, from raw material sourcing to consumption. HACCP relies on prevention at critical control points to ensure food safety before it reaches consumers. It is a "stage-gate" process for planning food safety, relying on anticipation of potential points of contamination. The HACCP is easy to develop and transferable to commercialization priorities since it is widely understood and already widely adopted.

Table 3.1 shows our perception of the equivalence between HACCP and the commercialization process. Using this logic, commercialization can be viewed as a multi-stage process with clear risk points. Each stage is assessed based on interview-derived risk themes and translated into controls specific to that stage.

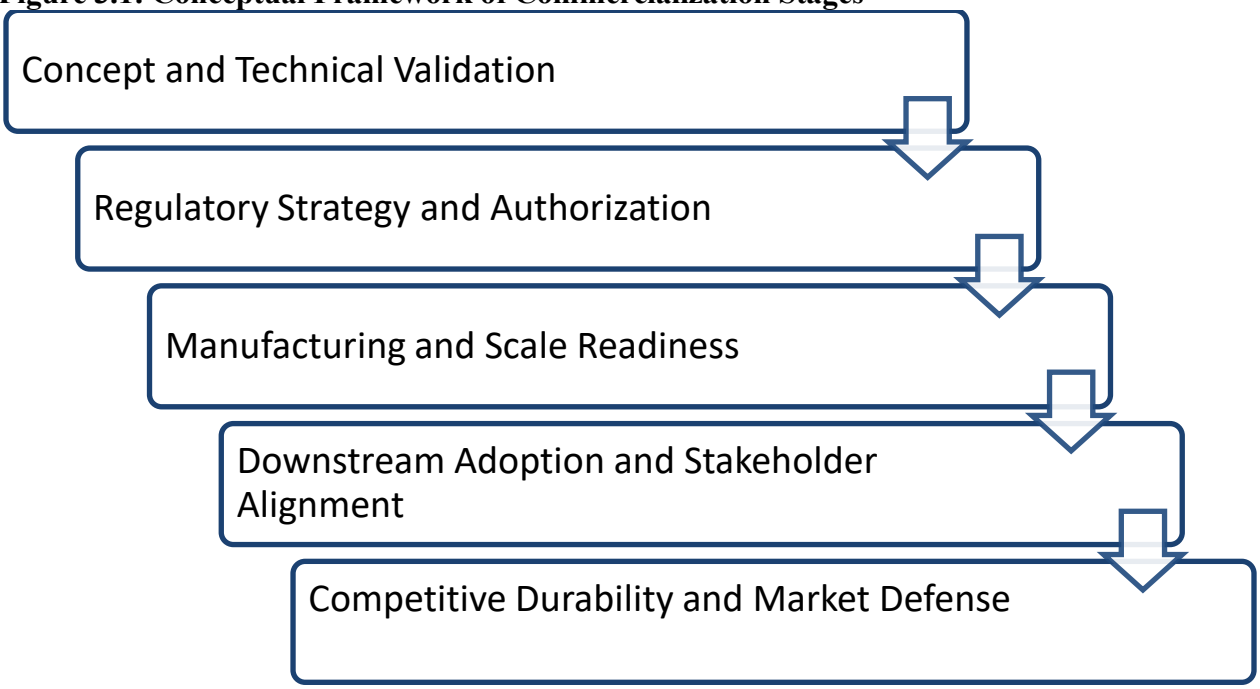
Table 3.1: HACCP-Commercialization Equivalence

HACCP	Commercialization Equivalent
Hazard	Commercialization risk factor
Critical Control Point	Stage-gate decision threshold
Critical Limit	Minimum readiness criteria for advancement
Monitoring	KPI tracking
Corrective Action	Strategic mitigation intervention

Figure 3.1 illustrates the primary commercialization stages used in this study. It provides the "Five Pillars" upon which commercialization success in this study rests. Each stage represents a distinct phase in the transition from technical development to sustained market deployment, with specific risks, decision thresholds, and coordination requirements.

These are the stages that provide input into the commercialization equivalent presented in Tabe 3.1 above.

Figure 3.1: Conceptual Framework of Commercialization Stages



Concept and Technical Validation refers to the initial stage in which the ingredient's functional performance is developed and tested. This stage establishes the proof of concept and confirms that it can perform in the desired applications.

Regulatory Strategy and Authorization involves defining the appropriate ingredient pathway and acquiring the necessary safety data and approvals for market entry. This stage assists in reducing downstream adoption uncertainty and establishes ingredient compliance.

Manufacturing and Scale Readiness addresses the ability to produce the ingredient at commercial volumes with consistent quality and cost efficiency. This includes process validation, supply chain readiness, and the ability to meet projected demand without compromising performance or economics.

Downstream Adoption and Stakeholder Alignment is the stage where potential customers evaluate and possibly adopt the innovation. It requires alignment among internal stakeholders, including R&D, regulatory, operations, quality, and commercial teams.

Competitive Durability and Market Defense focus on maintaining market advantage through various means, such as intellectual property, supply agreements, regulatory pathways, and first mover advantage. This stage ensures that early commercialization success can be preserved despite competitive pressure.

3.3 Selection of Respondents and Data Collection Methods

Participants were selected through the authors' industry connections and deliberately chosen to ensure the study reflected the viewpoints of professionals directly responsible for commercializing new food ingredients or consumer products. Instead of surveying broadly, the goal was to engage subject matter experts with practical experience in making real commercialization decisions. The criteria required participants to have direct involvement with at least one of the key areas essential to commercialization.

Twenty senior leadership professionals were recruited for this study. Participants included executive leadership of global ingredient companies and founders of rapidly growing startups, followed by senior innovation leaders within global CPG companies, business development and commercialization executives responsible for downstream adoption, regulatory affairs leaders overseeing global approval strategies, operational and quality executives responsible for manufacturing, and ingredient R&D leaders such as Senior Directors of Innovation and Heads of Formulation. Collectively, this group covers both ingredient and downstream adopters, ensuring cross-functional and cross-industry perspectives. This diversity is intentional, since failures rarely occur across a single function.

Data collection involved semi-structured interviews conducted both in person and virtually using a Survey Monkey questionnaire. The group was divided into in-person and virtual participants based on attendance at a US-based tradeshow and LinkedIn. All participants received the same set of questions, asked in a casual, informal setting. The interview guide was developed directly from the themes discussed in Chapter 2 and structured around the stages of commercialization. The questions explored the participants' background and experience, common failure patterns and root causes, stage-specific risks, sources of friction, preventive controls, and early warning signs. Success was also discussed to identify patterns of success, organizational alignment challenges, and competitive durability. Interviews lasted about 35 minutes, and participants were assured of anonymity to encourage truthful discussion. No proprietary data or confidential information was shared or requested. Emphasis was placed on experiences rather than on specific company performance.

3.4 Data Analysis and Transition to Findings

After collecting the data, the interview responses were downloaded from the questionnaire and organized into themes based on five commercialization pillars: Concept Validation, Regulatory Strategy, Manufacturing Scale-Up, Downstream Adoption, and Competitive Defense, rather than coding responses by individual roles. The chosen pillars reflect the main decision areas or phases in ingredient commercialization. This organization helped identify patterns related to failure, stage-specific risks, and factors influencing successful commercialization.

Once grouped, the responses were reviewed and analyzed using descriptive statistics. The means provide an estimate of average perceived risk across the pillars, while the median indicates the central tendency of responses. Standard deviation was used to

assess the level of agreement among respondents regarding the perceived severity of risk within each pillar. The results of this analysis are presented in the following chapter.

CHAPTER IV: EMPIRICAL FINDINGS

The following sections present empirical findings through a series of figures and tables that outline perceived commercialization risks, failure drivers, decision gates, and organizational factors associated with successful ingredient launches and adoption. These findings establish the empirical foundation for the structured commercialized pathway developed in the subsequent section.

4.1 Respondents Summary Statistics

The study uses responses from 20 professionals with direct, senior-level experience in ingredient commercialization, each having participated in ingredient launches across food and beverage markets. Participants were carefully selected based on their role in the ingredient commercialization decision-making process, ensuring coverage of the entire process, from development to market adoption. The purpose was not to produce inferential results but to offer insights into how senior leaders in different stages of the ingredient commercialization chain see critical aspects of the commercialization process. All responses were provided anonymously.

To facilitate meaningful analysis, respondents were categorized into three functional roles: commercial/business development, technical/R&D, and entrepreneurial/innovation. Respondents were asked to indicate the number of ingredients launched in four-year categories: Prior to 2020; 2020-2022; 2023-2025; and evenly distributed across the years. The results are summarized in Table 4.1. The table shows that half of the respondents were classified by role as commercial, 30% as technical and the remaining 20% as entrepreneurial. Over half of respondents (55%) reported involvement in four or more ingredient launches, indicating that the sample is skewed toward experienced

practitioners, which we believe strengthens the accuracy of the reported perceptions. Importantly, all role groups are sufficiently represented to enable meaningful cross-functional comparison. Regarding the historical launch periods, about 40% of new ingredient launches occurred almost evenly across the four other period categories while 25% and 20% respectively occurred in the 2023-2025 and before 2020 periods, respectively. The least number of launches, as may be expected, occurred during the Covid-19 years defined by 2020-2022.

Table 4.1: Distribution of Respondents by Role, Number of Launches, and Number Launches by Period (n = 20)

Category	Subcategory	Frequency	Percent (%)
Role Group	Commercial	10	50%
	Technical	4	30%
	Entrepreneurial	6	20%
	Total	**20**	**100%**
Number of Ingredient Launch Participation	1 launch	3	15%
	2 launches	4	20%
	3 launches	2	10%
	4 launches	11	55%
	Total	**20**	**100%**
Time Period of Launch	Evenly distributed	8	40%
	Before 2020	4	20%
	2020-2022	3	15%
	2023-2025	5	25%
	Total	**20**	**100%**

4.2 Commercialization Perceptions by Respondents' Role

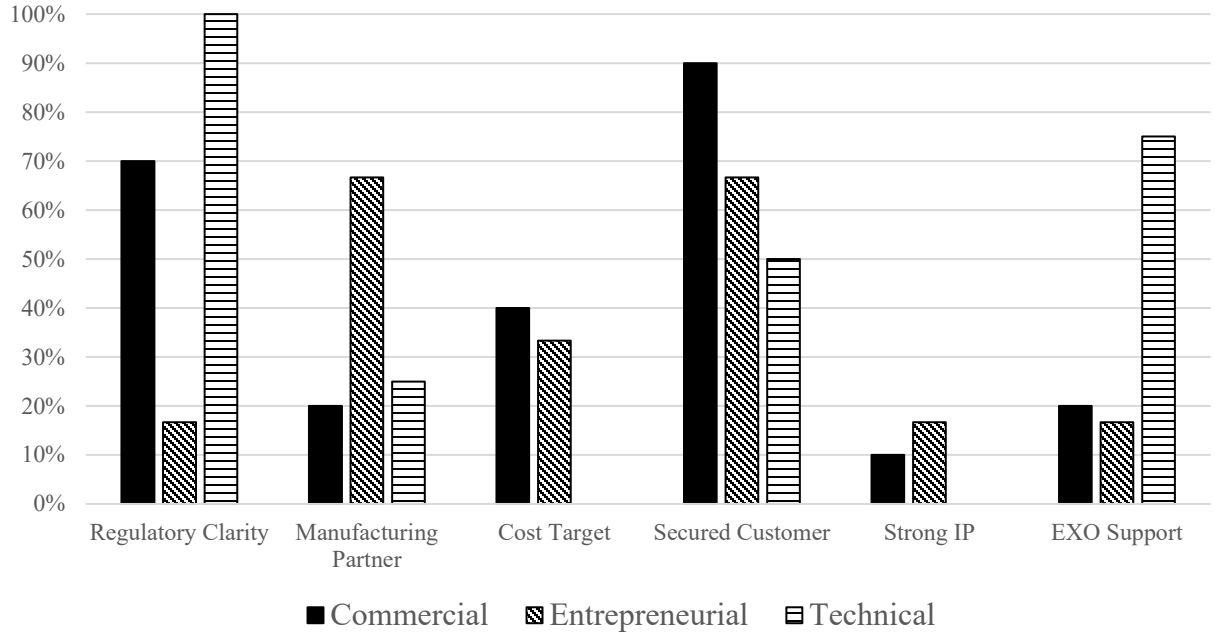
While Section 4.1 outlines the respondent group's structure, the next step is to determine whether these different commercialization perspectives lead to significant differences in how risks, decision points, and success factors are perceived. To address this, responses are compared across the three role groupings: commercial, technical, and entrepreneurial, to evaluate how role influences commercialization judgments.

4.2.1 Key Commercialization Success Decision Gates

Six key commercialization decision gates are identified in this study. They are Regulatory Clarity (1), Manufacturing Partner (2), Cost Target (3), Secured Customer (4), Strong Intellectual Property (IP) (5), and Executive Support (6). Each represents a critical decision gate in the innovation process that must be sufficiently addressed before advancing commercial efforts. Regulatory clarity involves establishing a clear regulatory pathway within the target geography. Manufacturing partner refers to the ability to identify a reliable partner who plans to produce ingredients once scaled, ideally with room for volume growth. The cost target signifies a competitive cost in use for the desired application and market. Secured customer indicates confirmed downstream demand through a committed customer or commercial agreement. Strong IP requires defensible intellectual property that safeguards innovation from competitive imitation. And lastly, executive support involves internal alignment, resource commitment, and strategic backing from organizational leadership.

Figure 4.1 shows there are clear differences in how role influences perceptions about the importance of key commercialization decision gates to commercialization success. It shows that 90% of respondents with commercialization roles prioritize securing customer commitment over everything else, with regulatory clarity coming in second for them, selected by 70% of them. On the other hand, respondents with technical roles overwhelmingly attributed importance of commercialization success to regulatory clarity (100%) and executive support (75%). For those with entrepreneurial roles, the commercialization decision gates contributing to commercialization success were securing a manufacturing partner and securing customer commitment, with 67% each.

Figure 4.1: Key Commercialization Success Decision Gates by Role (n = 20)



These patterns seem to indicate that roles influence perceptions about the importance of decision gates on commercialization success. The null hypothesis (H_0) is that there is no statistically significant difference between perceptions about importance of the commercialization decision gates for the success of the commercialization process by roles for all role pairs, *i and j*, and for each commercialization decision gate, *k.* The alternative hypothesis (HA) is that the different roles differ in their perceptions about the decision gates' importance for commercialization success. The hypotheses are presented in Equation 4.1.

$$\left.\begin{array}{l} H_0 : \rho_i^k = \rho_j^k \\ H_A : \rho_i^k \neq \rho_j^k \end{array}\right\} \quad \forall\, k = 1,2,...,6 \;\&\; i = 1,2,3,\, i \neq j \tag{0.1}$$

That is, the proportion of respondents with role *i* is equal to the proportion of respondents with role *j* for each commercialization decision gate, *k.*

As illustrated in Figure 4.1, 50% or more of all three roles identified securing customer commitment as essential for success. This suggests that, despite different perceptions of key commercialization decision gates across roles, certain decision points are universally regarded as critical success factors. Table 4.2 summarizes the hypotheses tests, indicating that while the null hypothesis cannot be rejected in most cases, it is rejected in a few specific cases. There is a statistically significant difference between commercial and entrepreneurial roles in their perceptions about the importance of regulatory clarity on commercialization success ($p < 0.05$). Likewise, the difference between the perceptions of respondents with technical and entrepreneurial roles regarding the importance of regulatory clarity on commercialization success was statistically significant ($p < 0.01$). The differences between the perceptions of respondents with commercial and technical roles and between those with technical and entrepreneurial roles about the importance of executive support were both also statistically significant ($p < 0.10$, respectively). For cost target, securing customers, and strong IP, the null hypotheses could not be rejected for all paired comparisons of roles, indicating broad alignment on these factors.

Table 4.2: Test of Hypotheses Results of Equality of Proportion by Role

Commercialization Success Decision Gate	Pr(|Z|>|z|)					
	Regulatory Clarity	Manufacturing Partner	Cost Target	Secured Customer	Strong IP	Executive Support
Commercial v. Entrepreneurial	0.040**	0.062*	0.790	0.240	0.690	0.870
Commercial v. Technical	0.217	0.837	0.135	0.099	0.510	0.052*
Technical v Entrepreneurial	0.010***	0.197	0.197	0.598	0.389	0.065*

Statistically significant difference at: Less than 1% (***); Less than 5% (**); and less than 10% (*).

4.2.2 Best Reason for Success

Respondents were asked to identify the primary reason for success, selecting from four predefined options: Adoption, Deployment, Price, and Cost. Each category reflects a distinct aspect of what constitutes "success" in the commercialization process. Adoption refers to the successful market uptake where the ingredient is integrated into products and achieves sustained use. Deployment reflects the ability to scale and operationalize the ingredients, as well as rolling out to a broader customer base in the market. Price reflects the market value of the ingredient, as indicated by what customers are willing to pay compared to the price set by the firm. Cost reflects the economic feasibility of producing the ingredient, including the ability to achieve tight margins and cost in use requirements. Together, these categories distinguish between downstream success drivers (adoption), operational execution (deployment), and economic viability (price and cost).

Table 4.3 shows that cost and price were not selected as reasons for success. This may be because respondents essentially see them as a given: wrong price and cost do not even get you into the market. We are therefore left with comparing adoption and deployment. Overall, 60% of respondents, regardless of role, selected adoption of the launched ingredient, while the remaining 40% chose deployment. Adoption was the most common choice among respondents with commercial and technical roles, with 60% and 75%, respectively. However, overall, there was no statistically significant difference between the proportions of respondents choosing between adoption and deployment ($p < 0.206$). Compared by role, there is no statistically significant difference between adoption and deployment for respondents with entrepreneurial and commercial roles, but the difference for those technical roles was statistically significant ($p < 0.0016$).

Table 4.3: Respondents Determine Best Reason for Success

Respondent's Role	Adoption	Deployment	Cost	Price
Commercial	60%	40%	0%	0%
Entrepreneurial	50%	50%	0%	0%
Technical	75%	25%	0%	0%
Total	**60%**	**40%**	**0%**	**0%**

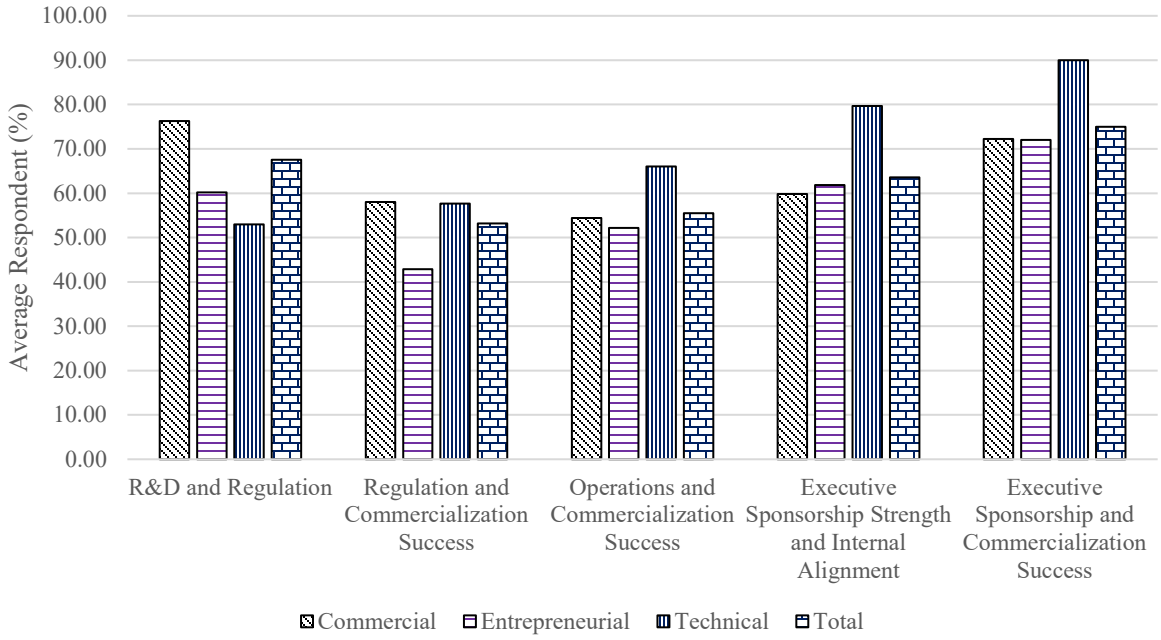
4.2.3 Organizational Alignment

Organizational alignment is critical for commercialization success. We identify five pairs of internal operational centers and evaluate respondents' perceptions about their alignment during the commercialization process. The pairs are: (1) R&D and Regulation; (2) Regulation and Commercialization Process; (3) Operations and Commercialization Process; (4) Executive Sponsorship Strength and Internal Alignment; and (5) Executive Sponsorship and Commercialization Process.

Figure 4.2 shows that overall alignment between Executive Sponsorship and Commercialization Process was perceived by respondents to be the most critical alignment for commercialization success, receiving 74.95% average rating. R&D and Regulation alignment was the second-most important with 67.53% average rating followed by Executive Sponsorship Strength and Internal Alignment with 63.58%. Respondents with commercialization roles scored R&D and Regulation alignment as the most important, with an average rating of 76.30%. However, for those with technical roles, the most important alignment was Executive Sponsorship and Commercialization Process, with an average rating of 90.00%. Respondents with technical roles prioritized alignments Operations and Commercialization Process, Executive Sponsorship Strength and Internal Alignment, Executive Sponsorship and Commercialization Process above both those with commercial and entrepreneurial roles. Further, there were no statistically significant differences

between commercial and entrepreneurial respondents for alignments between Regulation and Commercialization Process, Operations and Commercialization Process, Executive Sponsorship Strength and Internal, and Executive Sponsorship and Commercialization Process.

Figure 4.2: Internal Alignment Categories by Role (n = 20)



4.3 Commercialization Risk Concentration by Stage

Through the literature, we identified eight potential root causes of commercialization failure. They are (1) Organizational misalignment, (2) Insufficient technical validation, (3) Lack of cost competitiveness, (4) Weak downstream demand, (5) Regulatory delays or misalignment, (6) Scale-up challenges, (7) Capital constraints, and (8) Competitive pressure. These root causes may be organized into two broad groups: Those that are directly determined by the decisions the company makes (Internal); and those that are directly determined by the outcomes and decisions outside the company (External). For example, organizational misalignment is classified as an internal root cause because it is

determined solely by the behavior and decision-making processes in place within the organization. On the other hand, regulatory delays are external to the organization because the delays are often a result of processes the organization has no control over. Similarly, capital constraints are internal to the organization while weak downstream demand is dependent on customer response to the product, which is ultimately determined solely by those customers.

Respondents were asked to rank these potential root causes of commercialization failure by three categories: high; medium; and low. In addition to role-based differences in perception, the data also reveals how commercialization risk is distributed across development stages. Half of the respondents indicated that their product launch stalled at the downstream adoption. Another 30% stalled at the concept or technical validation stage, while 10% said their products stalled at the regulatory stage. This distribution indicates that commercialization failure is more likely to occur after technical feasibility is established, particularly during the transition from development to market adoption. Early-stage validation is important, but the greatest risk lies in translating technical success into sustained commercial traction.

Table 4.4 summarizes the average proportion of respondents across the three ranking categories for each root cause. Organizational misalignment is defined as existing when different stages along the commercialization pathway are not looking at the same data or not interpreting the data they have in the same way, and thereby making different decisions. The table shows that organizational misalignment is perceived as the leading cause of commercialization failure, with an average of about 63% of respondents selecting it as the highest root cause. Conversely, capital constraints and competitive pressure were identified

as low contributors to the root causes of commercialization failure, averaging 21.1% and 5.3%, respectively, in the high category, and 68.4% and 63.2%, respectively, in the low category, suggesting that internal execution challenges are perceived as more critical than external market forces. However, this ranking structure highlights perceived importance rather than definitive contribution, as respondents were required to distribute rankings across categories.

Table 4.4: Distribution of Root Causes of Commercialization Failure by Rank Proportion

Root Cause	Primary Source	Commercialization Failure Rank Proportion (%)		
		High	Medium	Low
Organizational Misalignment	Internal	63.2	26.3	10.5
Weak Downstream Demand	External	47.4	36.8	15.8
Insufficient Technical Validation	Internal	47.4	47.4	5.3
Regulatory Delays	External	42.1	42.1	15.8
Lack of Cost Competitiveness	Internal	36.8	63.2	0.0
Scale-Up Challenges	Internal	36.8	42.1	21.1
Capital Constraints	Internal	21.1	10.5	68.4
Competitive Pressure	External	5.3	31.6	63.2

Table 4.4 does not provide a clear enough picture of the overall ranking of the principal root causes of commercialization failure. To better isolate the most definitive contributions to failure, the rankings were coded into binary classification, where High and Medium rankings are defined to mean definite root causes of failure (1) and Low as low or no contribution to the root cause of failure (0). This approach removes forced ranking effects and provides a clearer view of which factors are consistently identified as true drivers of failure. Table 4.5 shows that the top root causes of commercialization failure were perceived to be mostly internal to the organization. For example, lack of cost

competitiveness may result from misunderstanding or underappreciation of novel ingredient commercialization cost. Likewise, organizational misalignment, as described above, may result from incongruence in the decisions by different leaders in the organization.

Table 4.5: Summary Statistics of Recoded Ranking of Root Causes of Commercialization Failure as Binary (High and Medium = Contributory; Low = Not Contributory)

Root Cause	Source	Mean	Std. dev.	CV
Lack of cost competitiveness	Internal	1.00	0.00	0.00
Insufficient technical validation	Internal	0.95	0.23	0.24
Organizational misalignment	Internal	0.89	0.32	0.35
Regulatory delays or misalignment	External	0.84	0.37	0.44
Weak downstream demand	External	0.84	0.37	0.44
Scale-up challenges	Internal	0.79	0.42	0.53
Competitive pressure	External	0.37	0.50	1.35
Capital constraints	Internal	0.32	0.48	1.51

Table 4.6 shows the ranking results using the binary (Table 4.5) of the pairwise correlation matrix of the perceptions about the eight root causes of commercialization failure. It shows that the correlation between the ranking of insufficient technical validation and scale-up challenges is positive (0.46) and statistically significant at the 5% level. That is, higher levels of insufficient technical validations are more likely to cause scale-up challenges, which will affect commercialization success. On the other hand, there is a negative and statistically significant correlation between scale-up challenges and capital constraints. This suggests that organizations are less likely to experience scale-up challenges in the absence of capital constraints. Although negative, the correlation between insufficient technical validation and weak downstream demand is not statistically significant. This is true of

several of the other pairwise correlations, indicating there is no perceptual correlation among the respondents about these root causes of commercialization failure.

Table 4.6: Pairwise Coorelation Matrix of Ranking of Root Causes of Commercialization Failure

Root Causes		1	2	3	4	5	6	7
1	**Insufficient technical validation**	1.00						
2	**Regulatory delays or misalignment**	-0.10	1.00					
3	**Scale-up challenges**	0.46*	-0.22	1.00				
4	**Lack of cost competitiveness**	.	.	.	.			
5	**Weak downstream demand**	-0.10	-0.19	0.13	.	1.00		
6	**Organizational misalignment**	-0.08	-0.15	-0.18	.	-0.15	1.00	
7	**Competitive pressure**	-0.31	-0.57*	-0.41	.	-0.27	0.26	1.00
8	**Capital constraints**	-0.35	0.29	-0.48*	.	-0.33	-0.50*	-0.05

Statistically significance level of 5% (*)

CHAPTER V: SUMMARY AND CONCLUSION

5.1 Summary

The empirical findings demonstrate that commercial success is primarily determined by downstream adoption rather than technical validation. Commercialization challenges are both role-dependent and structurally consistent. The functional roles influence how risks and decisions are perceived, particularly in areas such as regulatory clarity, technical readiness, and downstream adoption. At the same time, any divergence across roles highlights predictable areas of misalignment rather than isolated or random variation.

Taken together, the results indicate that commercialization failure is concentrated at predictable transition points, particularly where technical validation, cost competitiveness, and market adoption intersect. While respondents often attribute failure to organizational misalignment, the underlying drivers are more closely tied to execution gaps in achieving technical feasibility and economic viability at scale. These findings support the view that commercialization failure is structurally driven rather than random, reinforcing the need for a stage-gate commercialization framework that systematically identifies and manages these critical control points.

5.2 Conclusion: HACCP-Based Commercialization Framework

We draw on the foregoing summary of the research to propose a structured HACCP-inspired framework for managing commercialization risks. Recall from Figure 3.1 the reference made to HACCP. The framework identifies key phases in the commercialization process where failure is most likely to occur and provides critical control points that must be managed to progress forward.

The framework consists of five primary stages: Concept Validation, Regulatory Strategy, Manufacturing Scale-Up, Downstream Adoption, and Competitive Defense. Each stage represents a critical control point where specific risks must be identified, monitored, and mitigated before progressing further in the commercialization process.

Using this HACCP-based approach, commercialization can be reframed as a structured risk management process rather than a linear or experience-driven progression. By identifying and actively managing critical control points, organizations can detect failure risks earlier in the development process, before they transform into costly delays or unsuccessful launches. This approach shifts decision-making from reactive to proactive problem-solving, relying on the experts in each role to strategically create and implement a HACCP-inspired plan to address technical feasibility, cost competitiveness, and downstream adoption in a coordinated and systematic manner. The foregoing is summarized in Table 5.1.

5.3 Recommendations for Future Research

This research is actually a pilot project aimed at testing how roles affected perceptions about commercialization success. As a result, the survey breadth and depth were limited and only roles were explored at a very high level. While the study's results offer some insight into the perception of respondents about various success factors as influenced by their roles, there is more that could be done to provide a more detailed picture of how best to improve the commercialization process and its successful outcome. For the main study emanating from this pilot study, we will redesign the survey to collect more detailed information from respondents. We will also target a much larger sample than what we have here. The targeting of respondents in this survey was inherently biased because it focused on those who were attending an industry trade show or have personal

connections. For the main study, we will draw a representative sample using a listing of industry members. Recognizing the importance of roles in perceptions, we will use a cluster sample approach so that the sample reflects the proportion of each role within the industry. This study was weighted towards those in commercialization, and we do not know if that weight was accurate.

For the main study, we envision collecting more information about the respondents and their companies beyond their roles. For example, we would like to collect information about the company (turnover, market position, size of the different departments, principal products, etc.) as well as information about respondents (experience, education, gender, compensation mix, career trajectory, etc.). This future work will help us to fine-tune the proposed HACCP-based approach in this study and explore more intensely the pros and cons of its adoption vis-à-vis the traditional stage-gate process used in new product development.

Table 5.1: Proposed HACCP Adaptation to Novel Ingredient Commercialization Process

Control Point	Risk Focus	Critical Control	Failure Mode Identified in Study
Concept Validation	Insufficient technical validation, and/or lack of product-market fit. At this stage, the primary risk lies in overestimating the ingredient's functional performance or applicability. Validation must extend beyond laboratory efficacy to include application-specific performance under real-world conditions.	• Application-specific testing, not just ingredient validation • Early customer feedback (VOC) • Clear definition of target applications and value proposition	High correlation between insufficient technology validation and downstream scale-up challenges.
Regulatory Strategy	Unclear pathway to market, regulatory delays Regulatory uncertainty can delay commercialization timelines, but findings indicate it is not the primary driver of failure. However, a lack of early regulatory clarity can compound downstream risks.	• Defined regulatory pathway by geography • Early engagement with regulatory experts • Alignment of claims with regulatory constraints	Regulatory challenges are secondary to execution risks but must be addressed early to avoid compounding delays.
Manufacturing Scale-up	Scale-up challenges, cost escalation, process instability This stage represents one of the most critical transition points, where technical feasibility must translate into a manufacturable reality. Failures at this stage are often tied to inadequate early validation.	• Pilot-scale validation under production conditions • Process stability and yield consistency testing • Cost modeling under scaled conditions	Strong linkage between technical validation gaps and scale-up failure.
Downstream Adoption	Weak downstream adoption and demand, lack of customer commitment This stage is the most critical determinant of commercialization success. Findings consistently show that securing customer adoption outweighs all other success factors across roles.	• Early customer engagement and co-development • Confirmed commercial use cases • Alignment with customer formulation and cost constraints	Adoption is not an outcome; it must be engineered early in the process.
Competitive Defense	Weak IP, lack of differentiation, commoditization While not a primary cause of failure, competitive positioning becomes increasingly important post-adoption to sustain market pressure.	• Defensible intellectual property • Clear differentiation vs alternatives • Ongoing innovation and claim support	Competitive defense was not a primary failure mode, highlighting that most products likely fail before competitive dynamics become a factor.

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APPENDIX A

Ingredient Launch and Commercialization Survey

SECTION 1: Background

1. What best describes your primary role?

- ◯ Ingredient R&D
- ◯ Regulatory Affairs
- ◯ Manufacturing / Operations
- ◯ Business Development / Commercialization
- ◯ Executive Leadership
- ◯ Innovation (CPG)
- ◯ Founder / Entrepreneur
- ◯ Other (please specify)

2. How many ingredient launches have you directly participated in?

- ◯ 0
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4+

3. Over what time period were most of these launches?

- ◯ Primarily before 2020
- ◯ 2020–2022
- ◯ 2023–2024
- ◯ 2025
- ◯ Evenly distributed

SECTION 2: Failure Patterns

4. At which stage do ingredient launches most commonly stall?

- ◯ Concept / Technical Validation
- ◯ Regulatory Strategy
- ◯ Manufacturing Scale-Up
- ◯ Downstream Adoption
- ◯ Competitive Defense
- ◯ Other (please specify)

5. Rank the following root causes of failure (Drag to rank):

- ☰ ☐ Insufficient technical validation
- ☰ ☐ Regulatory delays or misalignment
- ☰ ☐ Scale-up challenges
- ☰ ☐ Lack of cost competitiveness
- ☰ ☐ Weak downstream demand
- ☰ ☐ Organizational misalignment
- ☰ ☐ Competitive pressure
- ☰ ☐ Capital constraints

6. Which of the following most often contributes to failure after technical validation? (Select up to 3)

- [ ] Unclear regulatory pathway
- [ ] Inadequate manufacturing readiness
- [ ] High cost of goods
- [ ] Lack of executive sponsorship
- [ ] Downstream resistance
- [ ] Weak value proposition
- [ ] Other (please specify)

SECTION 3: Stage-Based Risk Severity

7. Risk severity during Concept Validation

0 Not a major risk 3 5 extremely significant risk

8. Risk severity during Regulatory Strategy

0 Not a major risk 3 5 extremely significant risk

9. Risk Severity During Manufacturing Scale-Up

0 not a major risk 3 5 extremely significant riak

10. Risk severity during Downstream Adoption

0 not a major risk 3 5 extremely significant risk

11. Risk severity during Competitive Defense

0 not a major risk 3 5 extremely significant risk

SECTION 4: Adoption Friction

12. What most causes downstream manufacturers to hesitate?

- [ ] Regulatory Uncertainty
- [ ] Reformulation Cost
- [ ] Supply Reliability Concerns
- [ ] Price Premium
- [ ] Performance Uncertainity
- [ ] Internal Stakeholder Misalignment
- [ ] Lack of Consumer Demand
- [ ] Other (please specify)

13. What factor is most often underestimated?

- ◯ Time to scale
- ◯ Regulatory complexity
- ◯ Cost reduction timeline
- ◯ Stakeholder alignment
- ◯ Competitive imitation
- ◯ Capital requirements

SECTION 5: Commercialization Success Determinants

14. At what stage is commercialization success most strongly determined?

- ◯ Concept validation
- ◯ Regulatory approval
- ◯ Manufacturing readiness
- ◯ First customer adoption
- ◯ Competitive positioning

15. Which decision gates most increase probability of success? (Select up to 3)

- ☐ Clear regulatory pathway before scale
- ☐ Secured manufacturing partner
- ☐ Validated cost target
- ☐ Confirmed downstream customer commitment
- ☐ Strong IP protection
- ☐ Executive sponsorship

16. Before full commercialization, which KPI matters most?

- ◯ Cost of goods trajectory
- ◯ Regulatory clearance status
- ◯ Customer trials secured
- ◯ Manufacturing yield
- ◯ Time to scale

SECTION 6: Scale & Economics

17. On a scale of 0–5, how planned was the scale strategy?
0 = Completely reactive
5 = Fully planned from early development

18. Thinking about your most successful launch, which of the following would you select as the best reason for your success?

- ◯ Price
- ◯ Cost
- ◯ Adoption
- ◯ Deployment

SECTION 7: Organizational Alignment

Rate internal alignment during commercialization (0 = Poor | 5 = Strong)

19. R&D and Regulatory alignment

20. Regulatory and Commercial alignment

21. Operations and Commercial alignment

22. Executive sponsorship strength

23. On a scale of 0–10, how critical is executive sponsorship to commercialization success?

0 5 10

SECTION 8: Competitive Durability

24. What Intellectual Property protection mechanisms were used? (Select all that apply)

- [ ] Patents
- [ ] Trade secrets
- [ ] Exclusive supply agreements
- [ ] Regulatory data protection
- [ ] First-mover advantage
- [ ] None

25. How quickly did competitors respond?

- ◯ Within 6 months
- ◯ 6 - 12 months
- ◯ 1 - 2 years
- ◯ More than 2 years
- ◯ No meaningful timeline

Final Question

26. If you had to identify ONE factor that most determines commercialization success, what would it be?